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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/966,940	11/10/97	TAMARKIN	L 01994-0024 <sup>mk</sup>

KIMBERLY J PRIOR  
JONES & ASKEW  
191 PEACHTREE STREET N E  
37TH FLOOR  
ATLANTA GA 30303-1769

HM22/0317

EXAMINER

DELACROIX MUIRHEI, C

ART UNIT

PAPER NUMBER

1654

8

DATE MAILED: 03/17/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/966,940

Applicant(s)

TAMARKIN et al

Examiner

C. Delacroix-M

Group Art Unit

1654

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 12/23/98
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-26 is/are pending in the application.  
Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-26 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

#### **DETAILED ACTION**

The following is responsive to Applicant's election received Dec. 23, 1998.

Claims 1-26 are presented for prosecution on the merits.

#### ***Drawings***

1. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

#### ***Election/Restriction***

Applicant's provisional election of "TNF- $\alpha$ " and "Freund's complete adjuvant" is acknowledged.

The traversal of the restriction requirement has been considered and found persuasive. Accordingly, claims 1-26 are presented for prosecution on the merits.

#### ***Claim Objections***

2. Claims 23, 26 are objected to because of the following informalities: in claim 23, line 10, "phosphoipids" should read --phospholipids--. Furthermore, claim 26 is dependent upon a non-existent claim, i.e. claim 30. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

3. Claims 1, 4, 9, 10, 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 9, the term "admixture" is vague and indefinite because it is not clear how "admixture" is the same as a conjugate or complex wherein the colloidal gold is **bound** to the biologically-active factor as exemplified in Applicant's specification. Further clarification is respectfully requested.

In claims 4, 10, 12, the limitation "the immunologically toxic biologically-active factor" lacks antecedent basis in the claims.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5, 6, 8, 9, 11, 13, 19, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Shiosaka et al., 5,112,606.

Shiosaka discloses compositions comprising colloidal gold complexed with proteins and glucoproteins. See col. 2, lines 54-60; col. 3, lines 1-9. The compositions may be administered to a mammal to induce an immune response. Please claim 1; abstract.

Claims 19 and 21 are anticipated by Shiosaka because Shiosaka discloses administration of the same composition to a host using the method steps claimed by Applicant. Accordingly, targeted delivery of the biologically-active factor is inherent.

6. Claims 1-26 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9421288 ('288).

WO '288 discloses the invention substantially as claimed. Specifically, WO '288 discloses compositions and vaccines comprising colloidal metal, such as gold chloride or silver, in combination with a biologically active factor such as TNF- $\alpha$ . Said compositions/vaccines further include pharmaceutically acceptable carriers and Freund's complete adjuvant, respectively. Additionally, said compositions may be used to treat individuals suffering from cancer or immune related diseases. The vaccines may be also be administered to a mammal to vaccinate said mammal against a

normally toxic biologically-active factor. Preferred routes of administration are intramuscular and intravenous and the compositions may be administered singly or in multiple doses. Please refer to pages 1-10 and claims 1-22.

Claims 19 and 21 are anticipated by WO '288 because WO '288 discloses administration of the same composition to a host using the method steps claimed by Applicant. Accordingly, targeted delivery of the biologically-active factor is inherent.

**Conclusion**

Claims 1-26 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on (703) 308-0254. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

Mar. 13, 1999

  
Cecilia J. Tsang  
Supervisory Patent Examiner  
Technology Center 1600